

UNITED STATE EPARTMENT OF COMMERCE United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS

Washington, D.C. 20231

H /

FIRST NAMED INVENTOR ATTORNEY DOCKET NO. A FILING DATE / 11 A / 99 001560-372 021839 HM12/1031 **EXAMINER** BURNS DOANE SWECKER & MATHIS L L P MARX, I POST OFFICE BOX 1404 ALEXANDRIA VA 22313-1404 PAPER NUMBER ART UNIT 1651 10/31/01 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Adv	<i>isor</i> v	/ Actio	n
AUI	ioui y	/ ACUU	,,

Application No. **09/389,318**

Applicant(s)

Examiner

Art Unit

Irene Marx

1651

Suzuki et al.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. THE REPLY FILED Oct 19, 2001 Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. THE PERIOD FOR REPLY [check only a) or b)] a) The period for reply expires ____ ___ months from the mailing date of the final rejection. b) In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection. Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). A Notice of Appeal was filed on Oct 19, 2001 . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. 2. 🗆 The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees. 3. X The proposed amendment(s) will not be entered because: (a) X they raise new issues that would require further consideration and/or search. (See NOTE below); (b) X they raise the issue of new matter. (See NOTE below); (c) X they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) U they present additional claims without cancelling a corresponding number of finally rejected claims. 4. 🗆 Applicant's reply has overcome the following rejection(s): 5. 📖 Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s). The a) \square affidavit, b) \square exhibit, or c) \boxtimes request for reconsideration has been considered but does NOT place the 6. X application in condition for allowance because: see attachement 7. 🗌 The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection. 8. X For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any): Claim(s) allowed: none Claim(s) objected to: none Claim(s) rejected: 1, 3-7, 31, and 32; Claims 8,10-15,17-30 are non-elected. The proposed drawing correction filed on _____ a) \underline has b) \underline has not been approved by the Examiner. 10. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11. Other: **IRENE MARX** PRIMARY EXAMINER **ART UNIT 1651**

Serial No. 09/389318 Art Unit 1651

Note:

Claims 8, 10-15, and 17-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The proposed amendment raises new issues that would require further consideration and/or search with respect to the recitation in new claim 33 of "with agitation and an aeration rate of at least about 1 vvm", including issues under 35 U.S.C § 112 and of new matter. New issues requiring further consideration are raised also by the substitution of "has an ability to produce" to "produces", including new issues under 35 U.S.C §112 regarding process conditions, for example.

It is noted that applicant failed to respond to the request for clarification regarding identification of members of the genus *Mortierella*, subgenus *Mortierella*.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

With respect to the art rejections the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains having resistance to 4% of carbon source concentration by weight differ and, if so, to what extent in their ability to produce arachidonic acid, from the strains discussed in the references.

In addition, and as noted in the last Office action, the only strain shown to have the required ability and, in fact, to produce the touted amount of arachidonic acid is the deposited strain SAM 2197(See, e.g., Table 1) using glucose as carbon source in conjunction with yeast extract and under specific process conditions.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. <u>In re Dill</u>, 202 USPQ 805 (CCPA, 1979), <u>In re Lindner</u> 173 USPQ 356 (CCPA 1972), <u>In re Hyson</u>, 172 USPQ 399 (CCPA 1972), <u>In re Boesch</u>, 205 USPQ 215, (CCPA 1980), <u>In re Grasselli</u>, 218 USPQ 769 (Fed. Cir. 1983), <u>In re Clemens</u>, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Primary Examiner

Art Unit 1651